UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

JESSICA JACOBS, INDIVIDUALLY AND AS SPECIAL ADMINISTRATOR OF THE ESTATE OF CONNER ETHAN BUCHNER, A DECEASED MINOR,	**CASE NO.: 1:22-cv-02222**
PLAINTIFF,	**JURY TRIAL DEMANDED**
V.	
ABBOTT LABORATORIES, INC.,	
DEFENDANT.	

COMPLAINT

Plaintiff Jessica Jacobs, Individually and as Special Administrator of the Estate of Conner Ethan Buchner ("Baby B"), a deceased minor (hereinafter "Plaintiff" or "Baby B's Mother"), by and through the undersigned counsel, brings this Complaint against Abbott Laboratories, Inc. ("Abbott"). Plaintiff alleges the following upon personal knowledge as to Plaintiff's own acts and experiences and upon the investigation conducted by Plaintiff's attorneys:

NATURE OF THE ACTION

1. This action arises out of the catastrophic and preventable death of a newborn baby who died after he was given a cow's milk-based infant formula and/or fortifier, which ultimately caused the baby to develop necrotizing enterocolitis ("NEC").

2. NEC is a deadly intestinal disease characterized by inflammation and injury of the gut wall barrier that may advance to necrosis and perforating of the gut. Advanced cases of NEC may lead to surgery and death. Significantly higher rates of NEC have been found in premature babies with low birth weights who are fed cow's milk-based formula or fortifier products.

3. Companies who manufacture these products often mislabel and misrepresent the contents of the products to the public and the health care community, passing off these deadly products as similar to or even superior to human breast milk.

4. Plaintiff is the mother of Baby B who tragically died as a result of NEC.

5. Plaintiff brings this lawsuit against Abbott for claims arising from the direct and proximate result of Abbott's negligent, willful, and wrongful conduct in connection with the design, development, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, failure to warn, and/or sale of Abbott's cow-based products (hereinafter "Cow's Milk Products").

6. Upon information and belief, significant decisions and acts and omissions regarding the design, production, manufacturing, marketing, advertising, warnings and/or testing all occurred or emanated from Abbott's personnel and facilities in Illinois.

PARTIES

7. Baby B was born prematurely at Shands Jacksonville Hospital ("Shands Hospital") on November 5, 2008. He died on November 13, 2008, at only eight days old after developing NEC. Baby B developed NEC after being fed Cow's Milk Products, despite his mother never receiving the opportunity to attempt breastfeeding.

8. Plaintiff Jessica Jacobs, the mother of Baby B, is a citizen of the State of Georgia and resides in Warner Robins, Georgia. Plaintiff was appointed Special Administrator of Baby B's Estate by order of the Clerk of the Circuit Court in Lake County, Illinois. *See* Exhibit A. Plaintiff brings this action as personal representative for the wrongful death of Baby B, pursuant to § 740 ILCS 180/2.1., on behalf of Baby B's Estate and herself as a survivor thereof.

9. Defendant Abbott is an Illinois corporation with its principal place of business in

Abbott Park, Illinois. Abbott is a well-known manufacturer of Cow's Milk Products and markets many of its products under the "Similac" brand name.

10. Defendant Abbott advertises that it provides the "#1 Formula Brand, Backed by Science" and claims to have "over 90 years of innovations" in infant formula.[1]

JURISDICTION AND VENUE

11. This Court has jurisdiction over this case pursuant to 28 U.S.C. § 1332, as complete diversity exists between Plaintiff and Abbott, and the matter in controversy exceeds the sum of $75,000.00, exclusive of costs, interest, and attorneys' fees.

12. Abbott is subject to personal jurisdiction in this judicial District because Abbott is incorporated in the State of Illinois and maintains its principal place of business in this District.

13. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(1) because Abbott is incorporated in Illinois and has its principal place of business in this District.

FACTUAL ALLEGATIONS

BABY B WAS BORN PREMATURELY AND DIED FROM NEC AFTER BEING FED COW'S MILK PRODUCTS

14. Baby B was born at Shands Jacksonville Hospital on November 5, 2008. Baby B was preterm at 36 weeks with a low birth weight of 2.530kg and a length of 44.5cm.

15. Shortly after he was born, Baby B was sent to the Neonatal Intensive Care Unit (NICU) for respiratory distress. He was treated for presumed sepsis and given oxygen via nasal canula. Baby B was eventually stabilized.

16. Baby B's mother attempted to pump her own breast milk, but she could not produce enough. As an alternative, the health care providers and staff provided Baby B with NeoSure infant formula, a brand of Similac manufactured by Abbott.

[1] Abbott Nutrition, https://abbottnutrition.com/similac (last visited Apr. 27, 2022).

17. On November 6, 2008, no abnormalities were noted with Baby B's bowel sounds or his abdomen. The use of NeoSure continued and increased.

18. From November 7 to November 12, 2008, Baby B was noted to be consuming full NeoSure feeds.

19. On November 13, 2008, Baby B developed bloody stool and was diagnosed with NEC. He underwent an exploratory laparotomy, which determined he had two bowel perforation sites with severe hemorrhagic necrosis of bowel segment in between perforations. However, post operation, Baby B decompensated. He became hypotensive, bradycardic and was bleeding from all IV sites. Resuscitation was started, however, Baby B's condition continued to deteriorate.

20. Baby B was pronounced dead at 8 days old. The clinical and autopsy findings support that Baby B's cause of death was NEC, which led to septic shock and disseminated intravascular coagulation, which resulted in his sudden passing.

21. At the time of his death, Baby B's mother was unaware of the fact that he had been fed harmful Cow's Milk Products that caused or substantially contributed to the development of NEC and ultimately to his death.

NEC IS A DEADLY DISEASE THAT LARGELY AFFECTS PREMATURE INFANTS

22. According to the World Health Organization ("WHO"), babies born prematurely or "preterm," are defined as being born alive before 37 weeks of pregnancy are completed, like Baby B. The WHO estimates that approximately 15 million babies are born preterm every year.

23. Nutrition for preterm babies is significantly important. Because preterm babies typically have metabolic immaturity, poor gut function, and cannot coordinate sucking with breathing, it is not safe to feed preterm babies by mouth. Preterm babies also have special nutritional needs. Whereas a full-term infant takes about four to five months to double its birth

weight, a preterm baby with very low birth weight typically doubles in weight in several weeks, and that excess growth rate needs to be fueled nutritionally.

24. Up until the 1960s, preterm babies were most often fed human milk from either the baby's mother or a donor, but it did not meet the unique nutritional needs of preterm babies. Thereafter, cow's milk-based formula products became more popular, but still did not meet the nutritional needs. In the early 1980s, cow's milk-based products began to be specifically designed for preterm babies.

25. However, while the cow's milk products were good for bulking up preterm babies quickly, science and research have advanced in recent years confirming strong links between cow's milk products and NEC.

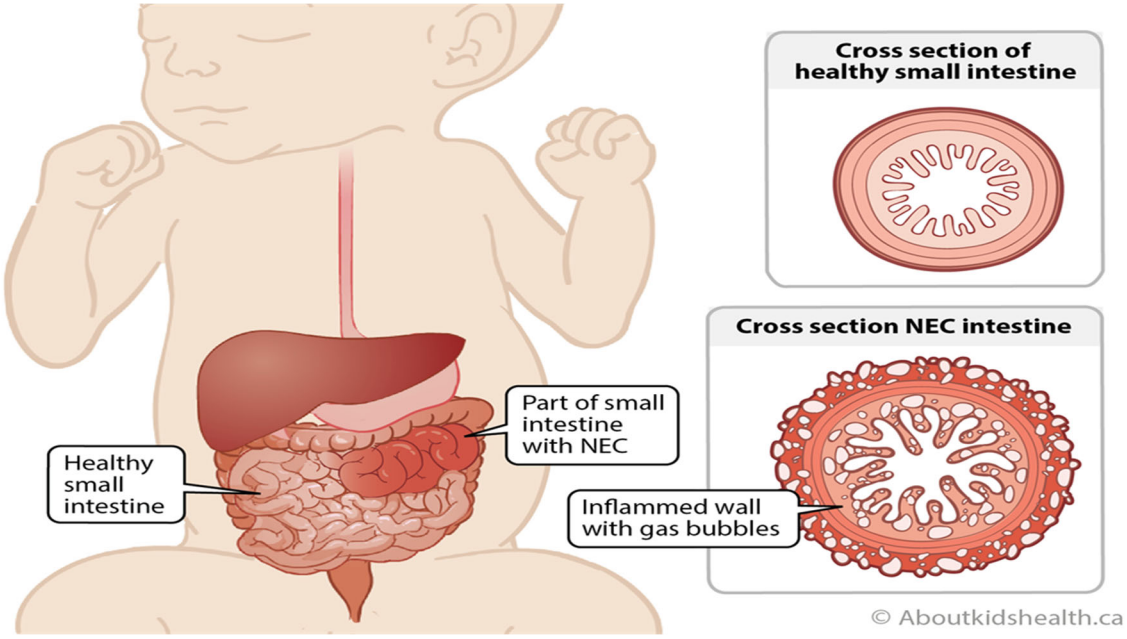
26. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting premature infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

27. Normally, the cells lining the lumen of a baby's intestinal wall have microvilli that magnify the surface area for available uptake. Nutrients are absorbed by these cells, transported through the cells, and released where they are then transported to the rest of the body through the bloodstream and lymphatic system. The cells keep out the bacteria and toxins that are present in the intestines which would be harmful if absorbed into the other tissues of the body.

28. The tight junctions between each cell play a major role in preventing the bacteria and toxins from entering the body.

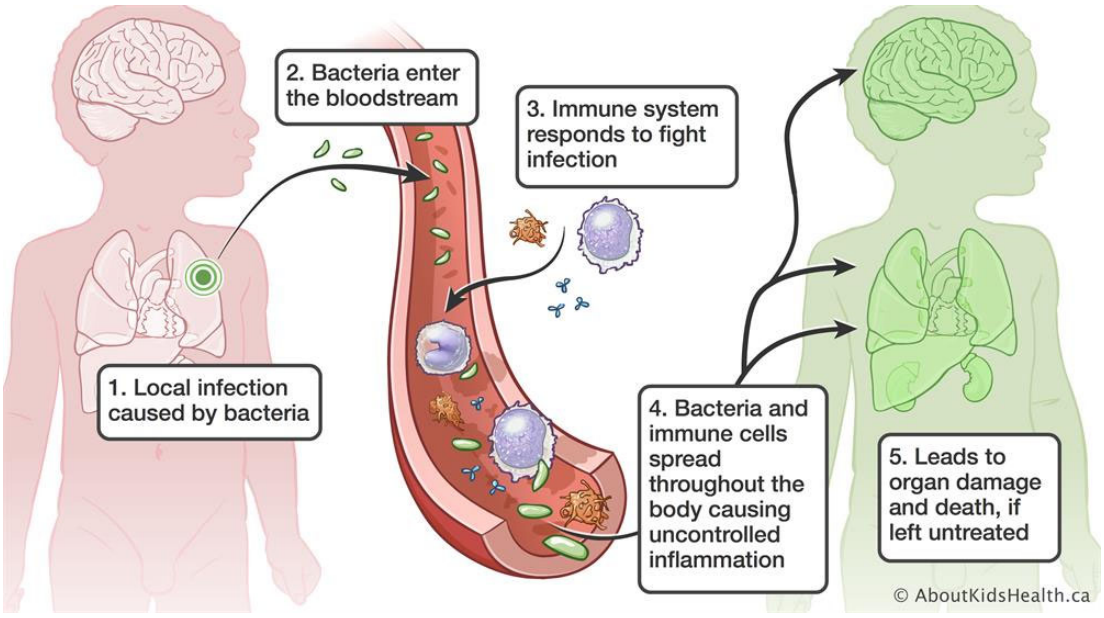
29. The diagram below demonstrates the inflammatory response to an infant's

intestines after he or she ingests cow's milk products, which causes the tight junctions to break down, and harmful bacteria and toxins to enter the infant's bloodstream and lymphatics[2]:



30. The image below on the left is a simplified view of the major organs of an infant's chest and abdomen, and the infant's circulatory system. By contrast, the infant depicted to the right is in distress, as is illustrated by the capillary bed where bacteria and toxins (shown in green) were transported from the intestines and spread to the rest of the body.[3] These toxins further breakdown and weaken the tight intercellular junctions, and as a result, bacteria, toxins, and plasma escape into the surrounding interstitial spaces resulting in a condition known as "third-spacing," and sepsis.

[2]About Kids Health, *Necrotizing Enterocolitis ("NEC")*, https://www.aboutkidshealth.ca/article?contentid=1769&language=english (last visited Apr. 27, 2022).
[3]About Kids Health, *Sepsis*, https://www.aboutkidshealth.ca/Article?contentid=2316&language=english (last visited Apr. 27, 2022).



THERE IS STRONG AND OVERWHELMING MEDICAL EVIDENCE ESTABLISHING THE EXTREME DANGERS THAT COW'S MILK PRODUCTS POSE FOR PREMATURE INFANTS

31. Science and research have confirmed strong links between cow's milk products and NEC causing and/or substantially contributing to death of premature infants, along with many other health complications and long-term risks to these infants.

32. For example, as far back as 1990, a prospective multicentre study on 926 premature infants found that NEC was six to ten times more common in exclusively formula-fed infants than in those fed breast milk alone and three times more common in those who received formula plus breast milk. Infants born at more than 30 weeks gestation confirmed that NEC was rare in those whose diet included breast milk, but it was 20 times more common in those fed formula only. A. Lucas, T. Cole, *Breast Milk and Neonatal Necrotizing Enterocolitis*, LANCET, 336: 1519-1523 (1990).

33. A study published in 2010 evaluated the health benefits of an exclusively human milk-based diet as compared to a diet with both human milk and bovine milk-based products in

extremely premature infants. The results show that premature infants fed an exclusively human milk-based diet were 90% less likely to develop surgical NEC as compared to a diet that included some bovine milk-based products. S. Sullivan, et al., *An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotizing Enterocolitis than a Death of Human Milk and Bovine Milk-Based Products*, JOURNAL OF PEDIATRICS, 156: 562-7 (2010).

34. In 2011, the U.S. Surgeon General published a report titled, "The Surgeon General's Call to Action to Support Breastfeeding." The report stated that "for vulnerable premature infants, formula feeding is associated with higher rates of [NEC]." U.S. Dep't of Health & Human Serv., Off. of Surgeon Gen., "*The Surgeon General's Call to Action to Support Breastfeeding*," p.1, (2011). It further stated that premature infants who are not breast fed are 138% more likely to develop NEC. *Id.*, Table 1, p.2.

35. In 2012, the American Academy of Pediatrics issued a policy statement that all premature infants should be fed an exclusive human milk diet because of the risk of NEC associated with the consumption of cow's milk products. The statement further urged that if a mother's own milk is unavailable, pasteurized donor milk should be used. A. Eidelman, et al., *Breastfeeding and the Use of Human Milk*, AMERICAN ACADEMY OF PEDIATRICS (2012).

36. Further, a 2013 study showed that 104 premature infants received an exclusive human milk-based diet and exceeded targeted growth standards and length, weight, and head circumference gain. A. Hair, et al., *Human Milk Feed Supports Adequate Growth in Infants ≤1250 Grams Birthweight*, BMC RESEARCH NOTES, 6-459 (2013). Thus, inadequate growth was proven to be a poor excuse for feeding premature infant's cow's milk products.

37. In another study published in 2014, it was reported that NEC is "a devastating disease of premature infants and is associated with significant morbidity and mortality." "While

the pathogenesis of NEC remains incompletely understood, it is well established that the risk is increased by the administration of infant formula and decreased by the administration of breast milk." Misty Good, et al., *Evidence Based Feeding Strategies Before and After the Development of Necrotizing Enterocolitis*, EXPERT REV CLIN IMMUNOL, 875-884 (2014).

38. In 2016, a large study supported previous findings that an exclusive human milk diet in extreme premature infants dramatically decreased the incidence of both medical and surgical NEC. This was the first study to compare rates of NEC after a feeding protocol implementation at multiple institutions and years of follow-up using an exclusive human milk diet. The authors concluded that the use of an exclusive human milk diet is associated with "significant benefits" for extremely premature infants and while evaluating the benefits of using an exclusive human milk-based protocol, "it appears that there were no feeding-related adverse outcomes." A. Hair, et al., *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk Based Diet*, BREASTFEEDING MEDICINE, 11-2 (2016).

39. A publication by the American Society for Nutrition in 2017 noted that, human milk has "been acknowledged as the best source of nutrition for premature infants and those at risk for NEC." The study compared the results from two randomized clinical trials on premature infants with severely low weight (between 500 and 1250 grams at birth) and compared the effect of bovine milk-based preterm infant formula to human milk as to the rate of NEC. Both trials found that an exclusive human milk diet resulted in a much lower incidence of NEC. While the study noted that bovine milk-based infant formulas provided consistent calories and were less expensive than human milk-based products, the bovine-based products significantly increase the risk of NEC and death. J. Shulhan, et al., *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, ASN ADV.

NUTR., 8(1):80-91 (2017).

ABBOTT USED FALSE AND MISLEADING ADVERTISEMENTS TO MARKET ITS COW'S MILK PRODUCTS, DESPITE EVIDENCE OF ITS DANGERS

40. Notwithstanding strong and overwhelming medical evidence establishing the extreme dangers that cow's milk products pose for premature infants, Abbott has marketed its Cow's Milk Products as an equally safe alternative to breast milk and has promoted these products as necessary for additional nutrition and growth. Specifically, Abbott has marketed its formulas and fortifiers as necessary for the growth and development of premature infants, when instead, these products pose a known and substantial risk to these babies.

41. One study estimates that formula manufacturers, like Abbott, spent $4.48 billion on marketing and promotion in 2014 alone. P. Baker, et al., *Global Trends and Patterns of Commercial Milk-based Formula Sales: Is An Unprecedented Infant and Young Child Feeding Transition Underway?,* PUBLIC HEALTH NUTRITION (2016).

42. Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. None of Abbott's marketing materials, including its promotional websites, reference the science showing how significantly its products increase the risk of NEC.

43. Abbott has also engaged in tactics to "hook" moms when they are most vulnerable. Abbott does this by offering free formula and other freebies and coupons in "gift baskets" given to mothers in hospitals, medical clinics, and even left at residential charities where out-of-town families stay when their babies are being treated for a prolonged period in the NICU. This is an attempt to create brand loyalty under the guise of a "medical blessing," so that these vulnerable parents continue to use formula to feed their babies after they leave the hospital, resulting in great expense to parents, significant risk to the babies, and substantial profit to Abbott.

44. In 1981, the World Health Assembly of the WHO recognized the abuse and dangers of infant formula marketing and developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, the negative effect of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

45. While Abbott acknowledges the Code and claims to support the effort to encourage mothers to breastfeed for as long as possible, its actions show that its commitment is frivolous.

46. For example, on Abbott's website it states: "We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren't breastfed for medical reasons or otherwise, infant formula is the only appropriate, safe alternative to meet babies' nutritional needs."[4] However, this statement ignores the existence of donor milk, as well as human milk-based formula.

47. Further, Abbott markets and sells multiple products specifically targeting premature infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to assist premature infants in reaching their growth targets.

48. Abbott also has a drop-down menu on its website that mothers can use to help choose the formula Abbott recommends. By clicking "Similac Products" and then "Preemies," the website directs the mother to another page about Similac NeoSure, another Cow's Milk

[4] Abbott, *Infant Formula Marketing*, https://www.abbott.com/policies/infant-formula-marketing.html (last visited Apr. 27, 2022).

Product. Abbott claims that Similac NeoSure "supports better gains in weight, length, and head circumference when compared to term infant formula."[5]

49. Abbott's website fails to mention of the risk of NEC and misleadingly suggests to vulnerable mothers that its Cow's Milk Products are safe for their infants.

50. Additionally, when Abbott recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called "Similac Human Milk Fortifier," as pictured below. This name is misleading because it suggests the product are derived from breast milk, when, in fact, it's cow's milk-based. For example, a study found that only 8.8 percent of parents surveyed in the NICU interpreted "human milk fortifier" as potentially meaning a cow's milk-based product.

51. Abbott regularly advertises its products as providing "complete nutrition for immune support and brain and eye development." In promoting these messages, Abbott regularly uses a variety of advertising methods including online, print, and TV commercials. The purpose

[5] Similac, https://www.similac.com/products.html?age=7119 (last visited Apr. 27, 2022).

of these advertisements is to ensure that new parents believe Abbott's infant feeding products are on par or superior to breastmilk. An example of Abbott's marketing to consumers and the healthcare community is provided below[6]:

52. In an Abbott advertisement for another Similac product, the ad states "when you are ready to turn to infant formula, but you don't want to compromise, look to Pure Bliss by Similac. Its modeled after breast milk." Abbott uses a scene of a mother bottle feeding her baby with a window that opens to a field and in small, light-colored lettering, writes, "No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows. Ingredients not genetically engineered." Abbott claims mothers should trust its "thoughtfully crafted" product which comes after "90 years of crafting" infant formula.[7]

53. Abbott has designed powerful misleading marketing campaigns to deceive parents into believing that: (1) Cow's Milk Products are safe, including for premature infants; (2) Cow's Milk Products are equal, or even superior, substitutes to breast milk; (3) Cow's Milk Products are

[6] Abbott Nutrition, https://prod7-similac-2015-com.abbottnutrition.com/ (last visited Apr. 27, 2022).
[7] Similac, https://www.similac.com/products/baby-formula/pure-bliss-powder/24-7oz.html (last visited Apr. 27, 2022).

necessary for proper growth and development of premature infants; and (4) physicians consider its Cow's Milk Products to be a first choice. This marketing scheme is employed despite Abbott knowing of and failing to warn of the extreme risks that its Cow's Milk Products pose to premature infants like Baby B.

ABBOTT FAILED TO ADEQUATELY WARN CONSUMERS OF THE DANGERS OF ITS COW'S MILK PRODUCTS

54. Abbott promotes the use of its Cow's Milk Products to parents, physicians, hospitals, and medical providers as safe products that are specifically needed by premature infants for adequate growth. This marketing is directed specifically to parents throughout the United States, including in Illinois.

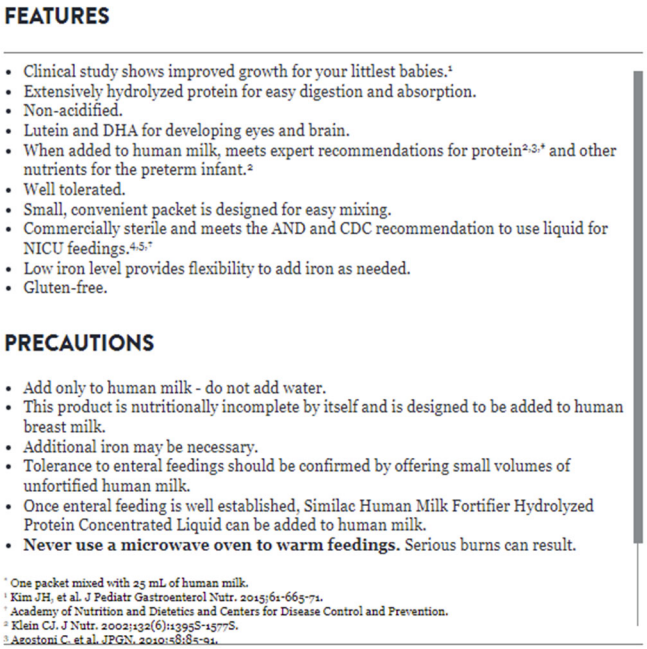
55. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

56. Despite knowledge of the significant health risks posed to premature infants ingesting Cow's Milk Products, including the significant risk of NEC and death, Abbott did not warn parents or medical providers of the risk of NEC, nor did Abbott provide any instructions or guidance on how to properly use its Cow's Milk Products so as to lower the risk or avoid NEC or death.

57. In fact, Abbott does not provide any warnings on its labeling, websites or marketing materials, that discuss the risk of NEC and death with use of its Cow's Milk Products.

58. For example, the warning on one of Abbott's Similac brand Cow's Milk Product states[8]:

[8] Abbott Nutrition, https://abbottnutrition.com/similac-human-milk-fortifier-concentrated-liquid (last visited Apr. 27, 2022).



FEATURES

- Clinical study shows improved growth for your littlest babies.[1]
- Extensively hydrolyzed protein for easy digestion and absorption.
- Non-acidified.
- Lutein and DHA for developing eyes and brain.
- When added to human milk, meets expert recommendations for protein[2,3,*] and other nutrients for the preterm infant.[2]
- Well tolerated.
- Small, convenient packet is designed for easy mixing.
- Commercially sterile and meets the AND and CDC recommendation to use liquid for NICU feedings.[4,5,7]
- Low iron level provides flexibility to add iron as needed.
- Gluten-free.

PRECAUTIONS

- Add only to human milk - do not add water.
- This product is nutritionally incomplete by itself and is designed to be added to human breast milk.
- Additional iron may be necessary.
- Tolerance to enteral feedings should be confirmed by offering small volumes of unfortified human milk.
- Once enteral feeding is well established, Similac Human Milk Fortifier Hydrolyzed Protein Concentrated Liquid can be added to human milk.
- **Never use a microwave oven to warm feedings.** Serious burns can result.

* One packet mixed with 25 mL of human milk.
[1] Kim JH, et al. J Pediatr Gastroenterol Nutr. 2015;61-665-71.
[*] Academy of Nutrition and Dietetics and Centers for Disease Control and Prevention.
[2] Klein CJ. J Nutr. 2002;132(6):1395S-1577S.
[3] Agostoni C, et al. JPGN. 2010;58:85-91.

TOLLING OF STATUTE OF LIMITATIONS

59. Due to the misleading marketing and lack of adequate warnings on its products, Plaintiff did not know and could not have known of the link between NEC and Cow's Milk Products like those at issue in this case and did not discover such a link until October 25, 2021.

60. Moreover, the misleading and improper marketing campaigns designed to promote its Cow's Milk Products as a safe alternative to breast milk products caused Plaintiff to believe that Abbott's products were safe for their intended use. Had Plaintiff known of these dangers or had Abbott adequately warned of these dangers at the time Baby B was exposed to Abbott's Cow's Milk Products, she would not have permitted such to be used on her son.

COUNT I: STRICT LIABILITY FOR DESIGN DEFECT

61. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

62. Abbott as the manufacturer and/or seller of the infant formulas at issue in this litigation, owed a duty to the consuming public in general, and Plaintiff in particular, to

manufacture, sell, and distribute its Similac products in a manner that was not unreasonably dangerous and is liable despite any care exercised to design a safe product.

63. Abbott also owed a duty to the consuming public in general, and Plaintiff in particular, to manufacture, sell, and distribute its Similac products in a manner that was merchantable and reasonably suited for its intended use.

64. At the time of manufacture, Abbott's Cow's Milk Products were not reasonably safe as designed. The likelihood that these products would cause NEC, serious injury, and death outweighed any burden to design infant feeding products that would not cause harm, and practical, feasible alternative designs would not have adversely affected the usefulness of the products.

65. Abbott knew (or reasonably should have known) that its products would be used to feed premature infants and that its use of cow's milk products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, it continued to sell and market its defective products as appropriate for premature infants.

66. Abbott's Similac NeoSure fed to Baby B was unreasonably dangerous.

67. The risks of feeding NeoSure to Baby B outweighed the benefits. An ordinary consumer would not expect such product to carry a significant risk of serious injury and death from NEC.

68. Abbott knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and/or death that its Cow's Milk Products do.

69. Abbott's Similac NeoSure contained cow's milk at the time it left the manufacturing facility.

70. Abbott failed to develop a human-based milk product which was safer for premature infants although it knew of this development and was aware of its superiority to the products that it offered.

71. Abbott failed to reformulate its products to reduce the risk of NEC, serious injury, and/or death, even though it knew of more effective alternative reformulations that would have made its products safer to use and not carry the added and significant risk of NEC.

72. As a direct result, Abbott's unreasonably dangerous products were fed to Baby B, which directly and proximately caused him to develop NEC and ultimately led to death.

73. As a direct and proximate result of Abbott's development, manufacturing, selling, and distribution of its unreasonably dangerous Cow's Milk Products, Plaintiff suffered significant emotional distress, loss of income, and other harms as her life has been significantly affected by the death of her son.

COUNT II: STRICT LIABILITY FOR FAILURE TO WARN

74. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

75. Abbott, as the manufacturer and/or seller of the infant products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiff in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of its products with premature infants, specifically including but not limited to the risk of NEC, serious injury, and death.

76. Abbott's duty to warn is part of its general duty to design, manufacture, and sell its infant products in a manner that is reasonably safe for its foreseeable uses. By designing Similac with cow's milk-based ingredients, Abbott undertook a duty to warn of the unreasonable risk of

harm posed by those ingredients, specifically including the increased risk of NEC, severe injury, and even death. The failure to warn makes the Cow's Milk Products at issue in this litigation unreasonably dangerous.

77. Specifically, Abbott breached its duty to warn of the foreseeable risks of the Cow's Milk Products at issue in this litigation because Abbott knew or should have known that its Cow's Milk Products would be fed to premature infants like Baby B, and that its products might cause those infants to develop NEC, severe injury, or death. However, Abbott failed to provide adequate warnings of those risks. Abbott also:

a. Failed to warn that Cow's Milk Products significantly increase the risk of NEC, severe injury, and death; and/or

b. Failed to warn that Cow's Milk Products are unsafe for premature infants like Baby B; and/or

c. Carried warnings and instructions on its products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

d. Failed to insert a large and prominent "black box" type warning that its Cow's Milk Products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or

e. Failed to disclose well-researched and well-established studies that linked cow's milk products to NEC and death in premature infants; and/or

f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital, that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed Abbott's products, notwithstanding their substantial risks; and/or

g. Failed to provide a warning in a method reasonably calculated or expected to reach an infant's parents; and/or

h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

78. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Abbott's products, Baby B was fed Cow's Milk Products, which caused him to develop NEC.

79. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and healthcare providers known of the extreme risk associated with feeding premature infants Cow's Milk Products, they would not have fed Baby B those products. Had Plaintiff known of the significant risks of feeding Baby B Cow's Milk Products, she would not have allowed such products to be fed to her child.

80. As a direct and proximate result of Abbott's failure to warn, Plaintiff suffered significant emotional distress, loss of income, and other harms as her life has been significantly affected by the death of her son.

COUNT III: NEGLIGENCE

81. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

82. Abbott, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiff in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

83. At all times relevant to this action, Baby B's health care providers used the products at issue in their intended manner and for their intended purpose.

84. Abbott, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the Cow's Milk Products at issue in this litigation and thereby breached its duty to the general public and Plaintiff.

85. Further, although Abbott knew or reasonably should have known at the time of production that its Cow's Milk Products significantly increased the risk of NEC, serious injury, and death, it failed to act in a reasonably prudent manner and breached its duty by:

a. Failing to warn that its Cow's Milk Products significantly increase the risk of NEC, severe injury, and death in premature infants; and/or

b. Failing to warn that its Cow's Milk Products are unsafe for premature infants like Baby B; and/or

c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

d. Failing to insert a large and prominent "black box" type warning that cow's milk products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or

e. Failing to provide well-researched and well-established studies that linked cow's milk products to NEC and death in premature infants: and/or

f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed Abbott's products, notwithstanding their substantial risks; and/or

g. Failing to provide a warning in a method reasonably calculated/expected to reach an infant's parents; and/or

h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk products.

86. Despite knowing for many years that the most vulnerable humans were suffering extreme harm related to the feeding of its Cow's Milk Products, Abbott failed to act in a reasonably prudent manner and breached its duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosing of adverse outcomes in infants who ingest its Cow's Milk Products.

87. As a direct and proximate result of Abbott's failure to act in a reasonably prudent manner and its breach of duty, Baby B was fed Cow's Milk Products, which caused him to develop NEC.

88. Had Abbott satisfied its duties to the consuming public in general, Baby B would not have been exposed to its unreasonably dangerous Cow's Milk Products.

89. As a further direct and proximate result of Abbott's negligent conduct, Plaintiff suffered significant emotional distress, loss of income, and other harms as her life has been significantly affected by the death of her son.

COUNT IV: INTENTIONAL MISREPRESENTATION

90. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

91. At all times relevant to this action, Baby B (and Plaintiff) used the products at issue in their intended manner and for their intended purpose.

92. Abbott, as the manufacturer and/or seller of the Cow's Milk Products at issue in this litigation, had a duty to the consuming public in general, and Plaintiff in particular, to provide truthful, accurate, and fulsome information about the risks and benefits of using its products when used in their intended manner and for their intended purpose.

93. Abbott breached its duty through misrepresentations made to consumers, physicians, and medical staff in its advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

94. Specifically, upon information and belief, Abbott made the following false statements of material fact on an ongoing and repeated basis and prior to the time Baby B was fed its products:

a. That its Cow's Milk Products were safe and beneficial for premature infants when it knew or should have known that its products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

b. That its Cow's Milk Products were necessary for the growth and nutrition of premature infants, when it knew or should have known that its products were not necessary to achieve adequate growth; and/or

c. That its Cow's Milk Products were safe for premature infants; and/or

d. That its Cow's Milk Products were necessary for optimum growth; and/or

e. That its Cow's Milk Products were similar or equivalent to breast milk; and/or

f. That its Cow's Milk Products were safe and more like breast milk than other infant products and that it had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in its products was still capable of causing NEC, serious injury, and death; and/or

g. That its Cow's Milk Products were based on up-to-date science, which made them safe for premature infants.

95. Abbott knew or reasonably should have known those misrepresentations to be false.

96. Abbott's misrepresentations were intended to, and in fact did, induce hospitals and health care providers, including Baby B's hospital and health care providers, to provide its Cow's Milk Products to infants, including Baby B.

97. Plaintiff was not aware that these misrepresentations were false and justifiably relied on them. Abbott's misrepresentations induced Plaintiff to allow Baby B to be fed Abbott's Cow's Milk Products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly. Had Abbott not committed these intentional misrepresentations, Baby B would not have been exposed to its unreasonably dangerous Cow's Milk Products.

98. Further, Abbott omitted the material fact that its Cow's Milk Products significantly increase the risk of NEC in premature infants.

99. As a direct and proximate result, Abbott's products were fed to Baby B, causing him to develop NEC, which ultimately led to his death.

100. As a further direct result, Plaintiff suffered significant emotional distress, loss of income, and other harms as her life has been significantly affected by the death of her son.

COUNT V: NEGLIGENT MISREPRESENTATION

101. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

102. At all times relevant to this action, Baby B (and Plaintiff) used the products at issue in their intended manner and for their intended purpose.

103. Abbott as the manufacturer and/or seller of the Cow's Milk Products at issue in this litigation, had a duty to the consuming public in general, and Plaintiff in particular, to provide truthful, accurate, and complete information about the risks and benefits of using its products when used in their intended manner and for their intended purpose.

104. In the course of its business, Abbott breached its duty through misrepresentations made to consumers, physicians, and medical staff in its advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

105. Specifically, upon information and belief, Abbott made the following false statements of material fact on an ongoing and repeated basis and prior to the time Baby B was fed its Cow's Milk Products:

a. That its Cow's Milk Products were safe and beneficial for premature infants when it knew or should have known that its products were unreasonably

dangerous and cause NEC, serious injury, and death in premature infants; and/or

b. That its Cow's Milk Products were necessary for the growth and nutrition of premature infants, when it knew or should have known that its products were not necessary to achieve adequate growth; and/or

c. That its Cow's Milk Products had no serious side effects, when it knew or should have known the contrary to be true; and/or

d. That its Cow's Milk Products were safe for premature infants; and/or

e. That its Cow's Milk Products were necessary for optimum growth; and/or

f. That its Cow's Milk Products were similar or equivalent to breast milk; and/or

g. That its Cow's Milk Products were safe and more like breast milk than other infant products and that they removed the harmful ingredients of cow's milk when, in fact, the cow's milk in its products was still capable of causing NEC, serious injury, and death; and/or

h. That its Cow's Milk Products were based on up-to-date science, which made them safe for premature infants.

106. Abbott was negligent or careless in not determining those representations to be false.

107. Abbott's misrepresentations were intended to and did in fact induce hospitals and health care providers, including Baby B's hospital and health care providers, to provide its Cow's Milk Products to babies, including Baby B.

108. Abbott's misrepresentations induced, and were intended to induce, Plaintiff to allow Baby B to be fed Abbott's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly. Had Abbott not committed these negligent misrepresentations, Baby B would not have been exposed to its unreasonably dangerous Cow's Milk Products.

109. Further, Abbott omitted the material fact that its Cow's Milk Products significantly increased the risk of NEC in premature infants.

110. As a direct and proximate result of Abbott's negligent conduct, its unreasonably dangerous products were fed to Baby B, causing him to develop NEC, which led to his death.

111. As a further direct result, Plaintiff suffered significant emotional distress, loss of income, and other harms as her life has been significantly affected by the death of her son.

COUNT VI: BREACH OF IMPLIED WARRANTIES

112. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

113. At all relevant times to this action, Baby B (and Plaintiff) used the products at issue in their intended manner and for their intended purpose.

114. The allegations contained in previous paragraphs set forth specific representations Abbott made to consumers, physicians, and medical staff through its advertising and promotional materials. The allegations contained in those paragraphs are incorporated herein.

115. Abbott implicitly warranted, through direct-to-consumer marketing, advertisements, and labels, that its Cow's Milk Products were safe and effective for reasonably anticipated uses, including use by premature infants.

116. Abbott implicitly warranted that its Cow's Milk Products were similar or equivalent to human milk.

117. Abbott implicitly warranted that its Cow's Milk Products were safe based upon current data and science.

118. Abbott's Cow's Milk Products did not conform to these implied representations because they cause serious injury (including NEC) when used to feed premature infants.

119. As a direct and proximate result of Abbott's breach of its implied warranties, Abbott's unreasonably dangerous products were fed to Baby B, causing him to develop NEC,

which ultimately caused his death

120. As a direct and proximate result of Abbott's breach of its implied warranties, Plaintiff has suffered significant emotional distress, loss of income and other harms as her life has been significantly affected by the death of her son.

COUNT VII: LOSS OF CONSORTIUM

121. Plaintiff incorporates by reference each of the proceeding paragraphs as if fully set forth herein.

122. Loss of filial consortium is a derivative claim. It is derivative of each of the claims and allegations above.

123. At all relevant times, Plaintiff was Baby B's mother.

124. As a result of Abbott's tortious conduct, Plaintiff suffered a loss of affection, companionship, society, and consortium of her child.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

a. For compensatory damages in an amount to be proven at trial;

b. Damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Abbott's conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For interest as permitted by law;

e. For attorneys' fees, expenses, and recoverable costs incurred in connection with this action; and

f. For such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby requests a jury trial for all claims triable.

Dated: April 28, 2022

Respectfully submitted,

/s/ Elizabeth A. Fegan
Elizabeth A. Fegan
FEGAN SCOTT LLC
150 S. Wacker Dr., 24th Floor
Chicago, IL 60606
Tel: (312) 741-1019
Fax: (312) 264-0100
beth@feganscott.com

Local Counsel for Plaintiff Jessica Jacobs, Individually and as Special Administrator of the Estate of Conner Ethan Buchner, a deceased minor

Shanon J. Carson
Peter Muhic
Dena Young
Najah Jacobs
BERGER MONTAGUE PC
1818 Market Street, Suite 3600
Philadelphia, PA 19103
Tel: (215) 875-3000
Fax: (215) 875-4604
scarson@bm.net
pmuhic@bm.net
dyoung@bm.net
njacobs@bm.net

Counsel for Plaintiff Jessica Jacobs, Individually and as Special Administrator of the Estate of Conner Ethan Buchner, a deceased minor